

Advanced Technologies in Trauma Critical Care Management

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KEYWORDS

- Innovation • Trauma critical care • Ultrasound • Hemodynamic monitoring
- Extracorporeal therapy • Wound management

KEY POINTS

- Bedside ultrasonography is now universal in the trauma intensive care unit (ICU) for rapid diagnosis in patients with unstable hemodynamics, for assessment of volume status, and for performing invasive procedures in the ICU.
- ICU monitors are becoming progressively more advanced and less invasive. Examples of modern monitoring technology include waveform analysis, complexity analysis, electrical velocimetry, smart monitoring, and telemonitoring.
- Advanced therapies now employed to improve patient outcomes in modern critical care include active thermoregulation, extracorporeal gas exchange, and extracorporeal blood purification.
- Trauma ICU patients commonly have large open wounds related to their injury or body cavities that require temporary closure. Negative pressure wound management has been widely used in the management of these large wounds and open body cavities.
- Novel technologies and therapies in critical care should be systematically evaluated by applying the recently defined Innovation Development Exploration Assessment Long-term study (IDEAL) criteria. Revisions to the US Food and Drug Administration approval system should also be considered to assure continued innovation in this field.

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INTRODUCTION

Postoperative surgical and trauma patients in the mid-1900s benefitted from the nexus of several concepts that led to the establishment of intensive care units (ICUs) in major medical centers across the country:

- Cohorting critically ill patients in a specialized unit
- Use of mechanical ventilation to support patients with respiratory failure
- Use of both non-invasive and invasive hemodynamic monitors
- Frequent measurement of blood gas values and other laboratory parameters.

The history of these advances and their application in modern critical care has been thoroughly reviewed by multiple expert authors.^{1–5} What sets the trauma ICU apart from other critical care environments is the frequent need for ongoing massive resuscitation and the periodic use of the ICU as an extension of the operating room for invasive procedures.⁶ In the trauma ICU, particular emphasis is placed on frequent reassessment of patients with severe injuries, on continuing the damage control therapy initiated in the emergency department or the operating room, and on providing an environment for the application of standardized treatment protocols for managing a range of clinical problems from traumatic brain injury to thromboprophylaxis in the acutely injured patient.^{7,8}

This care environment is characterized by a high degree of specialization and the use of advanced technologies; however, recent studies have also highlighted the importance of simple practices such as hand hygiene and a daily rounds checklist for improving outcomes.^{9,10} Furthermore, the benefits of ICU-based therapies are widely recognized as beneficial in both the developed and developing world, which should push researchers to continue to explore novel therapies that are both cost-conscious and scalable.¹¹

The following paragraphs describe a range of technologies that have transformed the care of trauma patients in the ICU in recent years. Although in some instances, the technology is not specific to a trauma population, the authors have chosen to discuss these particular applications, because they represent recent advances that have either advanced or revolutionized the care provided in the trauma ICU.

ULTRASOUND-BASED APPLICATIONS

Surgeon-performed ultrasound was first introduced as a real-time diagnostic tool in the early 1990s. Since that time, there has been a steady rise in the use of ultrasound for a range of applications in critically ill patients, to the point where ultrasound systems are ubiquitous in ICUs today. Surgeons and other intensivists caring for trauma patients use the various types of ultrasound equipment shown in **Table 1** on nearly a daily basis.¹²




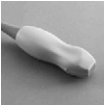
Several reviews on surgeon and intensivist-performed ultrasound provide a comprehensive overview of this broad topic.^{13–18} The following sections focus on the most common and emerging uses for ultrasound as a diagnostic, monitoring, and therapeutic tool in critically ill trauma patients.

Ultrasound for Diagnosis and Monitoring

Focused assessment with sonography for trauma examination

The Focused Assessment with Sonography for Trauma (FAST) examination was first promoted by Rozycki and colleagues.¹⁹ This study is performed in the trauma bay, where a low-frequency ultrasound probe is used to assess for fluid in the right upper quadrant, left upper quadrant, pericardium, and pelvis.²⁰ This examination has been adopted by trauma surgeons across the world and has also been used to good effect in combat casualty triage.²¹

Table 1
Types of ultrasound transducers commonly used in the ICU

Probe Type	Frequency Range ^a	Features	ICU Applications
Linear array 	13–5 MHz	Higher frequency range High resolution Shallow penetration Variable footprint depending on the probe design	CVL insertion PICC/PIV insertion A-line insertion Evaluation for DVT
Small curved array 	8–5 MHz	Intermediate frequency range Medium resolution Moderate penetration Small footprint	Follow-up FAST IVC evaluation Drain placement Thoracic imaging
Large curved array 	5–2 MHz	Lower frequency range Lower resolution Deeper penetration Wide footprint	Follow-up FAST IVC evaluation Drain placement
Phased array 	8–1 MHz	Wide frequency range Variable resolution Variable penetration Small footprint	Follow-up FAST IVC evaluation Drain placement Thoracic imaging Cardiac imaging

Abbreviations: CVL, central venous line; DVT, deep venous thrombosis; FAST, focused assessment with sonography for trauma; IVC, inferior vena cava; PIV, peripheral intravenous line.

^a By convention frequency ranges are listed from high to low frequency.

Photos courtesy of Sonosite, Inc., Bothell, WA; with permission.

Over time, the FAST examination has largely replaced diagnostic peritoneal lavage for identifying intra-abdominal fluid in trauma patients. Furthermore, with the addition of chest windows, the extended FAST can also rapidly diagnose a pneumothorax or hemothorax. By consensus, the learning curve for this examination has been defined as 200 examinations, of which at least half of these examinations should have positive findings.^{22,23} The sensitivity and specificity of this study for identifying intraperitoneal fluid in a blunt trauma patient range from 62% to 89% and 95% to 100%, respectively, depending on the patient population being evaluated, the experience of the sonographer, and the comparative gold standard study.²⁰

The role of the FAST examination in penetrating abdominal trauma remains unclear, as neither a positive nor negative result appears to reliably predict the need for operative intervention.²⁴ In contrast, in patients with penetrating anterior thoracoabdominal trauma, the subxyphoid window is very useful for identifying pericardial fluid warranting operative exploration. This examination has a sensitivity of up to 100% and specificity of 97%²⁵ with false-negatives primarily arising when pericardial blood decompresses into the pleural space.²⁶

At the authors' institutions, the FAST examination is typically performed during the trauma evaluation by emergency medicine and general surgery residents, with staff oversight. All images are saved for quality control review using subsequent computed tomography (CT) imaging or operative findings for determination of false-negative and

false-positive examinations. Management decisions based on the FAST findings are directly supervised by the staff trauma surgeon, who views the FAST images in real time.

In the ICU, follow-up FAST examinations can detect interval development of significant hemoperitoneum²⁷ and can identify complications of nonoperative management of solid organ injuries.²⁸ Thus, repeated FAST examinations can be an important diagnostic adjunct early in the ICU management of trauma patients.

Intensivist-diagnosed deep venous thrombosis

Trauma patients are at high risk for developing thromboembolic complications. At the same time, obtaining timely diagnostic ultrasound evaluation of the extremities is not always possible. Recent evidence suggests that intensivists trained in basic ultrasound can diagnose deep venous thrombosis (DVTs) with a high degree of accuracy thereby accelerating the treatment of this complication.²⁹

Thoracic ultrasound

Thoracic ultrasound has gained increased acceptance in the ICU as a diagnostic tool.³⁰ To minimize rib interference, a phased array or curved array probe with a small footprint is typically used for these examinations. The authors use chest ultrasound in the following manner:

- To identify a pneumothorax or hemothorax that needs to be drained acutely
- To differentiate a finding of consolidation versus effusion on radiograph.

Ultrasound to assess hypotension/fluid status

Both comprehensive and focused ultrasound examinations have been described as an adjunct to hemodynamic monitoring in trauma patients in the ICU. In particular, ultrasound can be useful in 2 scenarios:

- Hypotensive trauma patients in the ICU without an obvious source of hemodynamic instability
- Critically ill polytrauma patients with end-organ dysfunction and an unclear intravascular volume status.

In an acutely hypotensive trauma patient in the ICU, both transthoracic and tranesophageal ultrasound examinations have been advocated. Using a subxyphoid approach, inferior vena cava (IVC) diameter measurement with ultrasound can discriminate patients responsive to volume resuscitation as compared with nonresponders.³¹ Alternatively, a more comprehensive transesophageal echocardiography (TEE) examination can more specifically pinpoint the etiology of the hypotension and can guide both therapeutic interventions and ongoing resuscitation.¹⁸ The downside of the latter approach is the extensive additional training required to gain proficiency and the need for specialized equipment. However, as experience with ultrasound among intensivists broadens, use of TEE in the ICU will likely increase with time. In addition, relatively inexpensive disposable TEE probes such as the ClariTEE (ImaCor, Incorporated, Garden City, NY, USA) may lower barriers to using this approach.

In the more chronic trauma ICU patient, ultrasound imaging can be used to assess the patient's cardiac function and volume status. Two groups have advocated similar approaches using portable ultrasound technology in which several cardiac and IVC views are obtained to assess the patient's current physiologic state (**Fig. 1**).^{32–34} No patient outcomes are provided by either group; so further study in this area is required to guide future practice.

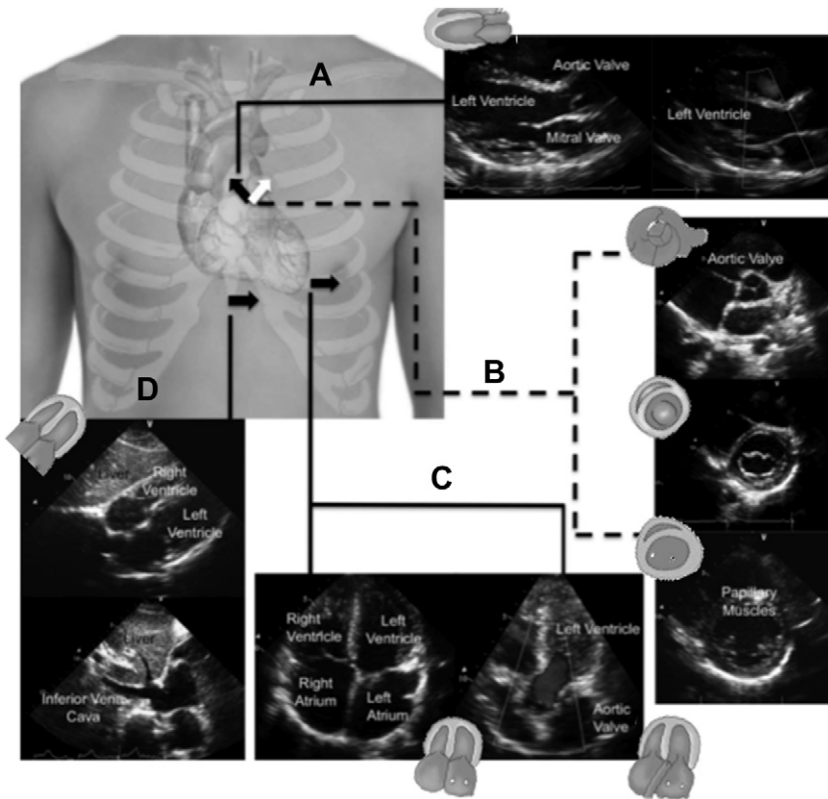


Fig. 1. Ultrasound assessment of volume status and cardiac function in the ICU uses a number of different sonographic windows. (A) Left parasternal long axis view. (B) Parasternal short axis view. (C) Apical 4-chamber view. (D) Subxyphoid view; caliber can be measured from the subxyphoid view through the liver. Arrowhead indicates the position of the marker on the ultrasound transducer. (Adapted from Ferrada P, Murthi S, Anand RJ, et al. Transthoracic focused rapid echocardiographic examination: real-time evaluation of fluid status in critically ill trauma patients. *J Trauma* 2011;70:57, with permission; and Kirk CR. Thumbnail guide to congenital heart disease. Available at: <http://www.crkirk.com/thumbail/index.htm>; with permission. Accessed December 3, 2011.)

ULTRASOUND-GUIDED INTERVENTIONS

Among trauma ICU patients, the most common ultrasound-guided interventions are vascular access and drain placement.³⁵ Ultrasound-guided placement of internal jugular lines has become the standard of care.³⁶ A high-frequency linear array probe is typically used either for a 1-time view of the target vein or in real time using a 1- or 2-person technique. Recently, ultrasound-guided subclavian central venous catheter placement has also been described.³⁷ However, the reliability of the landmark approach and the steep learning curve for the image-guided approach make ready adoption of this technique unlikely.

If the femoral vein is being considered for short-term access, an ultrasound examination for patency should be considered, especially in trauma patients in the ICU. In addition, the relationship of the vein to the artery can be variable, especially in younger patients, which becomes readily apparent with a quick ultrasound assessment.³⁸

Ultrasound can also be used for positioning peripherally inserted central catheters (PICC). This technique was recently described when a survey of the jugular vein

ipsilateral to the PICC insertion quickly ruled in or out malpositioning of the catheter.³⁹ If a malpositioned catheter was identified, ultrasound guidance permitted repositioning of the catheter without procedural interruption.

Arterial cannulation is also facilitated by ultrasound guidance. Radial artery catheter insertion is made more reliable with this technique using a high-frequency probe. Cannulation of the femoral artery can also be guided with ultrasound imaging whether for arterial line placement or insertion of an access sheath for diagnostic studies or therapeutic interventions.

Ultrasound can also be used to guide fluid aspiration and drain placement in the ICU. This most commonly includes ultrasound-guided thoracentesis and paracentesis. In both instances, ultrasound can be used to mark out the optimal needle insertion site and to evaluate for completeness of fluid evacuation. In the case of thoracentesis, ultrasound guidance reduces procedure time, increases the likelihood of accessing fluid on the first attempt, and reduces complications.^{40,41} For paracentesis, a low-frequency probe (eg, 2 MHz) is used to localize the intra-abdominal fluid, after which the abdominal wall should be assessed by either adjusting the image depth on a broad-bandwidth probe or by switching to a higher frequency probe (eg, 5 MHz). This technique facilitates access to the target fluid pocket while minimizing the risk of injury to the inferior epigastric vessels or abdominal wall varices.³⁵

Over the past 20 years, use of bedside ultrasound by surgeons for both diagnosis and management in critically ill trauma patients has grown dramatically. Consequently, surgeons should continue to take a leading role in defining standards for quality assurance and certification while also continuing to explore new and varied applications for this technology.

ADVANCES IN ICU MONITORING

Pulmonary Artery Catheter

The pulmonary artery catheter (PAC), once regarded as the gold standard of all hemodynamic monitors for extremely ill patients, has seen a dramatic decline in use over the past decade. Multiple well-designed clinical trials have failed to demonstrate any clinical advantage to its routine use in many populations including general ICU patients, septic patients, complex postsurgical patients, and those with severe respiratory dysfunction.^{42–46} Likely, this failure to demonstrate any morbidity or mortality benefit is related to the common error of assuming a pressure measurement is equivalent to volume or flow.⁴⁷ Clinicians are also well known to misinterpret the data provided by the PAC.^{48–51} Additionally, there are risks to the patient associated with placement and residence of a catheter within the pulmonary artery, including an increased risk of pulmonary embolism, bloodstream infections, a catheter-induced hypercoagulable state, and other technical complications.^{52–55} Finally, most data generated by the PAC can now be acquired through other less invasive technologies such as bedside echocardiography, central venous pressure monitoring, and cardiac electrical velocimetry.

These limitations aside, it is difficult to condemn an entire monitoring modality based on this evidence. There remain certain patients in whom multiple clinical conditions often generate an array of conflicting information, leaving the clinician with a confusing clinical impression. For these situations, an algorithm for the application of the PAC and interpretation of the data obtained may provide some insight to the patient's physiology⁵⁶; however, this approach has not been systematically evaluated. Another potential advantage to the PAC is that it lends itself to continuous waveform interpretation, which the authors use extensively in their preclinical laboratory studies, although no data currently exist to support this practice in the ICU.

Waveform Analysis

Multiple physiologic measurements taken in the ICU are acquired with relatively high sampling rates. These high sampling rates produce data that are far greater in volume and complexity than the human brain can adequately process and interpret in real time. Consequently, automated waveform analysis of those physiologic parameters captured in high granularity has the potential to increase understanding of the patient's physiology without adding additional invasive monitors. For example, instead of examining just the systolic and diastolic blood pressure on the arterial line tracing, waveform analysis allows interpretation of the change in slopes of the arterial line tracing, providing far more insight than the raw pressure values alone.

With the exception of fetal heart monitoring in the laboring mother, waveform variability and complexity analysis technologies have not matured enough to make their way into routine clinical practice; however, in time, these new technologies will very likely have a role in triage of trauma patients, prediction of ICU decompensation, and as tools to assess occult physiologic abnormalities that routinely go undetected with current monitoring paradigms.^{57–60} Monitoring approaches currently under active investigation in the ICU include plethysmography variability, arterial pressure and heart rate complexity analysis, continuous noninvasive hemoglobin determination, cardiac electrical velocimetry, and multiple vital sign integration with automated interpretation. **Fig. 2** illustrates the

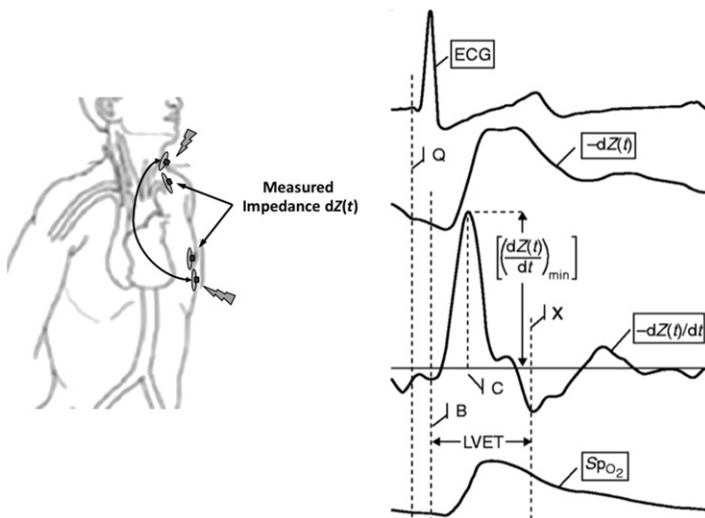


Fig. 2. Electrical velocimetry for calculating cardiac output. A small sinusoidal current is passed between a pair of electrodes, and the impedance to electrical flow conducted by the red cell mass within the thoracic cavity is measured (*left*). Shown are a representative electrocardiogram (ECG) tracing, ECG impedance waveform $-dZ(t)$, first derivative of the impedance waveform $dZ(t)/dt$, and pulse oximetry waveform SpO_2 . The first derivative of the impedance waveform ($dZ(t)/dt$) is used with an ECG to determine the beginning of electrical systole (Q), aortic valve opening (B), maximal deflection of the $dZ(t)/dt$ waveform (C), and the closing of the aortic valve (X). Stroke volume and cardiac output are calculated from these reference points. A high degree of correlation between cardiac output measured by Doppler and electrical velocimetry has been demonstrated. *Abbreviation:* LVET, left ventricular ejection time. (*Modified from* Schmidt C, Theilmeier G, Van Aken H, et al. Comparison of electrical velocimetry and transoesophageal Doppler echocardiography for measuring stroke volume and cardiac output. *Br J Anaesth* 2005;95:606; with permission.)

principles of electrical velocimetry for measuring cardiac output noninvasively as an example of the advanced monitoring devices that will be available for use in the ICU in the near future.

Smart Monitoring, Telemonitoring, and Telepresence

A smart monitor is any monitoring device that provides more information than simply the measured data. This can include waveform analysis as described previously, spectral interpretation, integration of multiple inputs, and decision support. This technology likely has emerged, in part, as a necessity to enable the clinician to integrate far more data than would otherwise be possible by simply examining an ICU flow sheet or the bedside monitors. One of the most practical applications of smart monitoring is automated decision support, which has been used for the resuscitation of burn patients and combat casualties.⁶¹ Additionally, multiple parameter inputs have already been successfully used in some ICUs,⁶² while others have demonstrated the utility of automated integration of existing vital sign data for triaging trauma patients.⁶³

Telemonitoring is another example of information integration and oversight that is gaining interest in modern ICU care. These systems stream all monitoring data including alarms, imaging studies, electronic medical record data, and often video images of the patient to an intensivist tasked with evaluating multiple patients. Recent results suggest this approach improves survival while decreasing cost,^{64,65} although others have not corroborated these results.⁶⁶ This concept can also be extended to telepresence using various fixed and mobile platforms that virtually bring the intensivist to the patient's bedside.^{67–70}

Decision Assist and Support

By leveraging biomedical engineering expertise and computer technology, various algorithms and automated bedside protocols have emerged that have the potential to optimize the delivery of critical care. One such example is the application of various software solutions to assist bedside nurses in optimizing glucose control in the ICU (eg, EndoTool, Hospira, Incorporated, Lake Forest, IL, USA). Others include the application of computerized decision assist algorithms to help clinicians manage hemorrhagic shock, burn shock resuscitation, and sepsis.⁷¹ Taking this concept 1 step further, closed-loop control systems are completely autonomous systems that adjust therapy based on real-time feedback. Examples of closed loop applications that are under active investigation for use in critical care include mechanical ventilation, sedation management, and intravenous fluid therapy.^{72–75}

ADVANCES IN ICU-BASED THERAPIES

The ICU affords the ideal environment to provide support or replacement of failing organ systems. Gas exchange support through mechanical ventilation has been the hallmark of ICU care for decades. Now even more advanced and novel therapies are appearing in ICUs with great regularity. This section focuses on some of these emerging therapeutic modalities.

Cooling for Neuroprotection

Cerebral anoxia represents the greatest cause of late mortality in patients who initially survive cardiopulmonary arrest. Consequently, adjuncts to neuroprotection during the vulnerable postresuscitation period have been the subject of numerous preclinical and clinical investigations. Following 2 positive prospective, randomized trials demonstrating a mortality benefit to systemic cooling in comatose survivors of a ventricular

tachycardia or ventricular fibrillation cardiac arrest, there has been great interest in this therapeutic modality.^{76,77} In the trauma population, extensions of this evidence have been applied to traumatic brain injury with refractory intracranial hypertension, anoxic brain injury from near-drowning, and both cold- and warm-water drownings.^{78–80}

The use of deep hypothermia after traumatic arrest is another example of this concept. Animal data suggest a significant survival benefit to this immediate cooling approach,^{81–83} and the first clinical trial is expected to begin shortly.⁸⁴

Therapeutic hypothermia in an ICU setting is best performed with the aid of a treatment algorithm to ensure the rate of cooling, the target temperature, the duration of cooling, the rate of rewarming, shivering control, and the frequency of laboratory draws are standardized. Equipment for performing therapeutic hypothermia consists of either an invasive or noninvasive thermoregulation device and a temperature probe, preferably in the esophagus or bladder (**Fig. 3**). Options for cooling range from ice packs to gel pads to catheters that fill with temperature-controlled saline. The authors' preference is to use a cooling catheter that produces very reliable temperature control during all phases of therapy, reduces the burden of nursing care especially during the rewarming phase, and minimizes contact with the patient's vulnerable skin. The catheter should be discontinued after completion of therapy due to a theoretical risk of thromboembolic complications.

Gas Exchange

Support of both oxygenation and ventilation with a mechanical ventilator has been a constant in critical care from the very beginning. Although this technology has evolved from negative pressure ventilators to microprocessor-based equipment with digital displays, the core concept of using the lungs for gas exchange has never changed. Advances in the use of this technology include the current standard of lung-protective ventilation, which has reduced mortality from respiratory failure,⁸⁵ and new ventilator modes such as airway pressure release ventilation (APRV).⁸⁶ However, in patients with severe respiratory failure, even with optimal ventilator management, up to one-third still die with their disease. Recent clinical evidence and technological improvements have led to a renewed interest in using extracorporeal gas exchange in

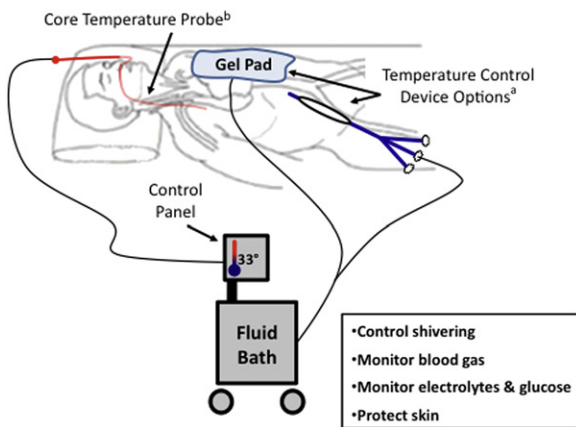


Fig. 3. Setup for therapeutic hypothermia or active thermoregulation. ^a Shown are a cooling gel pad and an invasive thermoregulation catheter as 2 temperature control options. ^b Core temperature can be measured by a pulmonary artery catheter, esophageal probe, bladder probe, or rectal probe.

this patient population to avoid barotrauma, volutrauma, and biotrauma while also permitting early physical therapy.⁸⁷

The components of an extracorporeal life support (ECLS) circuit include a mechanical pump, a gas exchange membrane, a heat exchanger, and pressure monitors (Fig. 4). Venovenous ECLS (vvECLS) is used in most cases of adult respiratory failure, as it can provide all of the gas exchange needs of most adult patients using modern membranes made of polymethylpentene (PMP). In select cases of isolated hypercapnic respiratory failure, a low-flow arteriovenous pumpless gas exchange circuit can rapidly normalize the PaCO_2 . If circulatory support is required, venoarterial ECLS (vaECLS) becomes necessary.

ECLS can be safely used in adult trauma patients. This advanced therapy should be done in an experienced center with clearly defined indications for initiating ECLS, established treatment protocols, and a staff well versed in ECLS circuit management.⁸⁸ In such centers, this therapy can be applied in patients with high-grade air leaks from tracheobronchial injuries, large pulmonary emboli with hemodynamic compromise, and in cases of right heart failure and hypoxemia following lung resection or pneumonectomy for trauma. In cases of severe accidental hypothermia, vvECLS can rapidly restore normothermia due to the high blood flow rates and the efficiency of the integrated heat exchanger in modern gas exchange membranes.⁸⁹

Extracorporeal Blood Purification

Renal replacement therapy is the most common extracorporeal blood purification modality used in modern ICUs for the purposes of metabolic and volume management in the setting of acute kidney injury. Intermittent renal replacement strategies in the ICU include intermittent hemodialysis (IHD) for hemodynamically stable patients and sustained low-efficiency dialysis (SLED), a hybrid technique that extends IHD over a longer period of time, for those who are hemodynamically unstable. Continuous renal replacement modalities include continuous venovenous hemofiltration (CVVH), hemodialysis (CVVHD) and hemodiafiltration (CVVHDF). At comparable doses, studies have failed to demonstrate an advantage of IHD over continuous modalities.⁹⁰

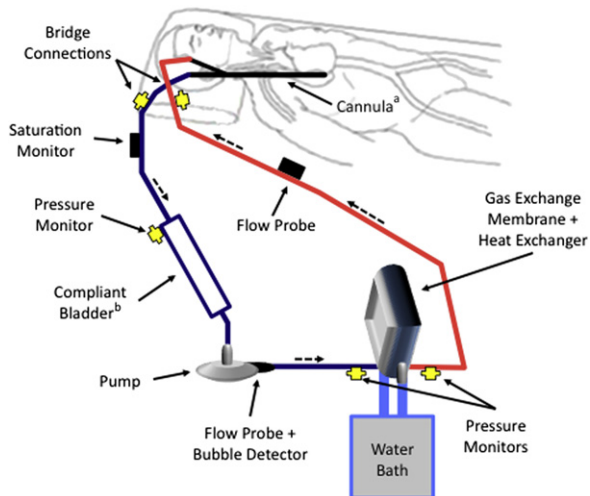


Fig. 4. Schematic of a vvECLS circuit. ^a A double lumen venous cannula (27–31 Fr) for single-site vvECLS is illustrated. ^b Optional with a centrifugal pump.

However, it has become evident that a minimum acceptable dose of therapy exists and likely needs to be achieved for optimal care. Trying to achieve a higher dose of therapy with daily IHD and SLED or higher dose CVVHDF has not improved outcomes.⁹¹ Future areas of investigation include patient selection and timing of renal replacement therapy, identifying alternative and more sensitive biomarkers of renal injury, and timing of renal replacement therapy termination.

Recently, there has been a paradigm shift among the nephrology and critical care communities toward broadening the scope of blood purification toward various extrarenal therapies. Extracorporeal blood purification for the purpose of immune modulation in sepsis and other types of shock, liver support, and combining various extracorporeal organ support modalities such as lung, kidney and liver into 1 comprehensive multiple organ support therapy (MOST) have all been described.⁹²

WOUND MANAGEMENT

No discussion of paradigm shifts and technological breakthroughs in trauma critical care would be complete without mention of negative pressure wound therapy. From open body cavities to fasciotomy incisions, this therapy has transformed both acute and chronic wound care over the past decade. This approach has been applied to almost every conceivable wound⁹³ and has proven beneficial in even the austere environment of combat casualty care.⁹⁴

Damage Control Closure

Temporary closure techniques of the open abdomen have evolved significantly since the introduction of damage control surgery.^{95,96} When considering an approach to temporary closure of the abdominal cavity, the following criteria must be met:

- Can be fashioned quickly with readily available supplies
- Underlying organs (eg, bowel, liver), wound edges, and fascial layers are protected
- A sterile dressing is maintained for hours to days
- Effluent from the wound is collected so that it does not macerate the tissues.

Vacuum-assisted closure readily meets all of these principles, and variations on this approach have been used in a variety of practice settings from resource-limited trauma centers⁹⁷ and austere combat environments⁹⁸ to high-volume urban academic centers.^{99,100}

Vacuum-assisted damage control closure of the abdomen can be applied using either a commercially available product or an expedient setup with supplies commonly used in the operating room. Two commercially available body cavity closure devices include the ABThera (Kinetic Concepts, Incorporated, San Antonio, TX, USA) and the RENASYS-F/AB Abdominal Dressing Kit (Smith & Nephew, Incorporated, St. Petersburg, FL, USA). Alternatively, an expedient temporary closure approach for the abdominal cavity is illustrated in **Fig. 5**. If definitive closure is contraindicated or impossible, to avoid losing abdominal domain, the authors often combine a vacuum-assisted closure method with some form of low level fascial tension such as a Wittmann Patch (Starsurgical, Incorporated, Burlington, WI, USA) or a sheet of mesh that can be serially tightened. In these cases, the authors are careful to maintain a nonadherent barrier between the bowel and these adjunctive closure devices to minimize bowel trauma and the risk of developing an enteroatmospheric fistula.

The concept of temporary thoracotomy closure has been recently described and may become more widely accepted in time.¹⁰¹ Rather than packing the chest, the authors prefer to use a modified negative pressure wound closure. In these situations,

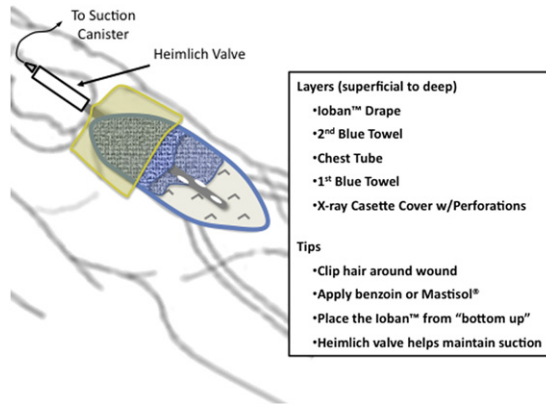


Fig. 5. Damage control temporary abdominal closure, which protects the bowel, the fascia, and the skin while controlling and monitoring fluid output. This technique is referred to as a vacuum pack (VP).

the authors first insert 2 or 3 chest tubes and position them as usual. A sterile nonadherent layer such as a single ply radiography cassette cover (without fenestrations) is then placed over the lung and the chest tubes to partition the intrathoracic space from the superficial wound space. A negative pressure wound sponge, operating room towel, or laparotomy pad is then placed in the wound, and suction is applied to this with either a commercial vacuum system or low-level continuous wall suction (eg, 75–125 mm Hg).

Negative Pressure Wound Therapy

Severely injured patients who require ongoing management in the ICU often have large wounds. These include fasciotomy wounds, degloving injuries, open fractures, traumatic amputation sites, and large torso or perineal wounds. After thorough debridement of devitalized tissue, removal of contamination, and confirming hemostasis, a vacuum-assisted dressing can be applied to the wound bed. For burn wounds or abrasions adjacent to wound, the authors apply a layer of XEROFORM petrolatum gauze (Covidien, Mansfield, MA, USA) to the area and place it in continuity with the negative pressure dressing. If the wound is significantly contaminated, an active fungal or mold infection is suspected, or soft tissue viability is questionable, the authors do not apply a vacuum-assisted dressing at the index procedure and use gauze dressings instead. In these cases, the authors moisten the gauze with saline, mafenide acetate (Sulfamylon), or a Sulfamylon/amphotericin mixture depending on the level of suspicion for infection in the wound.

As with temporary closure of body cavities, a vacuum-assisted dressing is an interim management strategy that allows stabilization of the wound bed and wound edges between serial washouts. During this interim period, patients experience less pain as bedside dressing changes are no longer necessary, and nursing staff can direct time and attention to other aspects of the patient's care.

For large wounds or previously contaminated wounds, the authors' approach is to return the patient to the operating room in 24 to 72 hours (depending on the appearance of the wound at the last evaluation) for re-examination of the wound, assessment of muscle and soft tissue viability, additional debridement, and thorough irrigation. This can also be done in the ICU under sedation, particularly if the patient is tenuous from a hemodynamic or respiratory standpoint.

There are several pitfalls with using such a dressing for a large wound:

- Suction failure leading to accumulation of infected fluid in the wound bed
- Bleeding into the sponge or canister
- Delayed re-evaluation of the wound, leading to regression of the wound bed.

Manufacturers have attempted to incorporate safety alarms that disable the pump and alert the care team to a problem if the previously mentioned issues arise. However, vigilance with frequent reassessment of the dressing and surrounding tissues and aggressive attention to alarms is always required to ensure safe and effective negative pressure wound management strategy.⁹³

The timing of definitive wound closure with either sutures or skin grafting is a matter of ongoing debate and investigation.¹⁰² In some instances, wound closure by secondary intention using serial vacuum-assisted dressing changes is deemed optimal. However, the authors' approach is more often to close these wounds once the patient's nutritional status is optimized, and the wound has healthy edges with no evidence of infection. Following delayed closure, the authors typically apply a vacuum-assisted incisional dressing. This can be done with a conventional vacuum dressing or with premade commercial products for this application (eg, Prevena Incision Management System, Kinetic Concepts, Incorporated, San Antonio, TX, USA). These dressings consist of an occlusive dressing placed directly on the wound with small fenestrations for fluid evacuation. A negative pressure sponge or gauze dressing is then applied over this layer. The authors remove this dressing in 3 to 5 days and typically transition to no dressing so long as there is no ongoing drainage from the wound.

EVALUATION AND IMPLEMENTATION OF NOVEL TECHNOLOGIES AND THERAPIES

The evolutionary and revolutionary concepts presented in this article have radically transformed the overall paradigm of critical care and the trauma ICU environment over the past decade. In some instances, these changes have occurred after careful consideration with a relative abundance of clinical evidence (eg, adult ECLS and therapeutic hypothermia for neuroprotection). In others, practical expedience drove the paradigm shift with very little evidence to support such a radical transition (eg, vacuum-assisted wound management). Going forward, as new concepts and ideas emerge, how should the trauma and surgical communities find balance between these 2 extremes? On the 1 hand, introducing unproven technologies on an unsuspecting public can have disastrous consequences, while on the other, stifling innovation or burying good ideas in a mire of red tape is counter to the very nature of the specialty of critical care. The following paragraphs suggest an approach to this dilemma with regards to evaluating current novel therapies and future innovations in the ICU.

IDEAL Criteria and US Food and Drug Administration Considerations

In 2009, a multidisciplinary commission met at Oxford University to discuss innovation and advancement in the surgical specialties.^{103–105} The objective of this commission was to promote surgical innovation while preventing future technological breakthroughs or innovative therapies from getting beyond a so-called tipping point of use before being reasonably evaluated. The quintessential example where the latter occurred was the widespread adoption of laparoscopic cholecystectomy prior to a careful evaluation of the risks and benefits of this surgical approach. The conclusion of this commission was that new ideas or evolutionary therapies need to be evaluated using an IDEAL framework as illustrated in **Box 1**. Using this approach, ideas that fill a capability gap or address a clinical need, such as smart monitors or negative

Box 1**IDEAL Steps for evaluating novel technologies or therapies****Innovation (stages 0–1)**

Initial procedures or early application of therapy

Animal studies (stage 0) and human studies (stage 1) explore proof of concept and safety

Informed consent including alternatives (from patient or legally authorized representative [LAR])

If time permits, inform hospital leadership

Report new procedure or therapy regardless of outcome

Need to develop infrastructure and systems for such reporting

Recent example: pyloric transposition¹⁰⁶

Development (Stage 2a)

Pilot study for innovation refinement (typically no more than 30 patients)

Protocols should be registered (eg, www.clinicaltrials.gov)

Approval by institutional review board (IRB) and possibly an ethics committee

Informed consent including alternatives (from patient or LAR)

Establish a risk minimization review process (eg, data safety monitoring board)

Report consecutive series of patients without omission

Include selection criteria, denominator of patients potentially eligible, and refinements

Recent example: ileostomy for fulminant *Clostridium difficile* colitis¹⁰⁷

Exploration (stage 2b)

Larger possibly multicenter study (typically hundreds of patients in total)

Uniformity of physician implementation across centers is essential

IRB approval and informed consent including alternatives (from patient or LAR)

Learning curve data will become available

Collect data prospectively in a systematic fashion

Report a range of outcomes including technical, clinical, and patient-reported

Report quality control measures applied to ensure uniformity of practice and use of therapy

Report numbers of patients seeking the new therapy if possible

Recent example: minimally invasive esophagectomy¹⁰⁸

Assessment (stage 3)

Randomized trial to assess effectiveness versus standard therapy

Consider alternative designs if randomized control trial not feasible or ethical (eg, case-control study)

Recent example: Conventional ventilatory support versus Extracorporeal membrane oxygenation for Severe Adult Respiratory failure (CESAR) trial for adult ECLS⁸⁸

Long-term study (Stage 4)

Assessment of long-term outcomes and surveillance for rare complications

Best accomplished through establishment of a registry

Recent example: endovascular management of blunt aortic injuries¹⁰⁹

pressure wound therapy, can be vetted in a systematic fashion without unduly delaying clinical availability if a benefit is demonstrated.

A related matter in the area of technology development that at once hinders the introduction of safe technology in this country while also permitting the introduction of unproven devices is the Food and Drug Administration (FDA) approval process. At present, device approval by the FDA for some devices is based on the arcane concept of legacy approval.^{110,111} This process allows the introduction of technology into the medical community without first demonstrating safety, much less benefit. In contrast, if a device is not felt to be substantially equivalent to some already approved device, it must be evaluated through the premarket approval (PMA) process, which may swing too far in the other direction of an exorbitantly expensive overevaluation in some cases. There must be a better, more balanced approach to this process in the future that the surgical community should demand to ensure new technology is evaluated in a safe, timely, cost-effective fashion going forward.

Examples

Some of the emerging concepts where the IDEAL framework can be applied are apparent in the current surgical literature (see **Box 1**). Examples in trauma management include novel resuscitation strategies for exsanguination shock,¹¹² balloon aortic occlusion for pelvic or torso trauma with hemodynamic instability,^{113,114} whole blood transfusion for trauma resuscitation,¹¹⁵ and rib fracture stabilization.¹¹⁶

In each instance, an evolutionary or revolutionary idea is being promoted to treat a high-risk clinical problem with relatively few viable options at present. The challenge is to responsibly evaluate these concepts with individualized levels of clinical study, often with the support and oversight of an appropriate national organization. Funding for these evaluations should consist of a balance of local institutional funds, funds from private foundations, support from national research institutes, and in some cases industry partners that can and should shoulder some of the burden of expense as is done in the area of pharmaceutical development. By following the IDEAL approach, innovation can continue at an appropriate and safe pace with less risk of finding that costly interventions have no clinical utility or even worse cause harm only after their widespread implementation.

SUMMARY

This article illustrated the transformation that has occurred in the critical care of the most severely injured trauma patients. The universal application of bedside ultrasound imaging has greatly enhanced the ICU toolkit for diagnosis, monitoring, and interventional procedural guidance. Today's monitors are becoming more focused on derivative information while also becoming generally less invasive. Temperature regulation is becoming widely recognized as a valuable treatment strategy, and the ability to target and maintain a specific temperature or rate of cooling/rewarming has been enhanced by new technology. Extracorporeal organ support or replacement for gas exchange and blood purification is becoming more commonplace in ICUs as clinical evidence for the merits of this approach builds. Finally, the management of open body cavities and large wounds has been transformed through the application of negative pressure. As these ideas advance and other ideas emerge, it is imperative that surgeons balance rapid development with circumspect evaluation of these ideas. Adoption of the IDEAL framework should make the process of innovation both more systematic and more streamlined, although significant changes to the FDA approval system are needed to ensure The United States' continued place on the cutting edge of critical care trauma therapy.

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